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No. 89-243

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,
v.
MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF FOR AMICI CURIAE ZIMMER, INC. AND BRISTOL-MYERS CO. IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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September 11, 1989

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MOTION OF ZIMMER, INC. AND BRISTOL-MYERS CO. FOR LEAVE TO FILE BRIEF OF AMICI CURIAE IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

Zimmer, Inc. is a manufacturer of medical devices and, in particular orthopedic implants to repair or reconstruct crippling skeletal defects. It is the holder of patents for many medical devices and expends considerable resources in developing innovative new devices. Its many patented medical devices are subject to approval by the

Food and Drug Administration ("FDA"). Bristol-Myers Co. is the parent company to Zimmer.

Petitioner Eli Lilly and Company ("Lilly") is seeking a writ of certiorari to review the decision of the United States Court of Appeals for the Federal Circuit interpreting 35 U.S.C. § 271(e)(1) as providing that certain "experimental" uses of a patented medical device in connection with submission of data to the FDA are not patent infringements. That decision, which came as a complete surprise to members of the medical device manufacturing community familiar with the statute, may be expected to have a substantial adverse economic effect on the medical device businesses of Zimmer and Bristol-Myers and of other similarly situated medical device manufacturers. In addition, the decision will have a substantial adverse effect on innovation in such medical device businesses. Therefore, both Zimmer and Bristol-Myers have a strong interest in review of that decision. Accordingly, both companies move this Court for leave to file their brief as amici curiae in this matter.

The accompanying proposed amici curiae brief sets out the arguments that Zimmer and Bristol-Myers wish to make to the Court concerning the reasons for granting Lilly's petition for a writ of certiorari. Zimmer and Bristol-Myers respectfully submit that, as members of the medical device industry with patented products potentially affected by the decision of the Circuit Court in this matter—but as companies without a direct interest in the specific products being contested—they are in a position to offer a useful perspective to the Court on the issues presented. Zimmer and Bristol-Myers thus request that their motion be granted and that their amici curiae brief be considered by the Court in the context of the pending petition for a writ of certiorari.

Counsel for Zimmer and Bristol-Myers has contacted counsel for the parties to seek their consent to filing of this brief. Counsel for Lilly has consented in writing.[1] Counsel for Medtronics has withheld its consent.

Respectfully submitted,

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[1] *See* Letter dated August 25, 1989 from Timothy J. Malloy, counsel of record for Lilly, to Donald O. Beers consenting to filing of *amicus* brief by Zimmer and Bristol-Myers. This letter is being filed with the Clerk with this motion.

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BRIEF OF AMICI CURIAE ZIMMER, INC. AND BRISTOL-MYERS CO. IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

INTEREST OF AMICI CURIAE

Zimmer, Inc., a manufacturer of medical devices, and Bristol-Myers Co., its parent corporation (hereafter referred to collectively as "Zimmer") file this brief as amici curiae in support of the petition of Eli Lilly and Company ("Lilly") for a writ of certiorari to review the decision of the Court of Appeals for the Federal Circuit in this matter. In that decision, issued on March 29, 1989, the Circuit Court interpreted 35 U.S.C. § 271(e)(1) to apply to medical devices as well as drugs, thus cur-

tailing the patent protection applicable to medical devices. If the decision is allowed to stand it will have potentially enormous adverse economic effects on the business of Zimmer and similarly situated manufacturers of medical devices.[1] More importantly, affirming this decision will curtail innovation by all United States manufacturers of medical devices at a time when innovation is greatly needed to address the numerous health care problems of our aging population.

SUMMARY OF ARGUMENT[2]

The decision below interpreted a provision of the Drug Price Competition and Patent Term Restoration Act of 1984[3] to state that it is not an act of infringement to make, use, or sell a patented medical device for uses reasonably related to the development and submission of information to the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act. That provision, codified at 35 U.S.C. § 271(e)(1), was written to allow limited testing of *drugs* during patent terms—testing that would not involve sales of the infringing products to potential customers of the patent owner. Congress never intended the statute to apply to *non-drug* products, as both the statute's terms and its legislative history make clear. Because medical devices differ from drugs in their development and regulation in significant ways, the effects of Section 271(e)(1) on innovation in the medical device industry are different from, and much greater than, the statute's effects on

[1] The medical device industry is of substantial importance to the United States economy, involving an estimated more than $24 billion in shipments for 1989, with an international trade surplus estimated at $1.3 billion. U.S. Dept. of Commerce, *U.S. Industrial Outlook 1989* 32-1 (1989).

[2] Amici adopt the statement of the issues and of the case included in the Lilly petition.

[3] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

drug innovation. The ramifications of the Circuit Court's decision are of such consequence, to amici and to the country generally, that the Court should grant certiorari. Because the decision is quite clearly wrong, summary reversal is appropriate.

ARGUMENT

I. THE DECISION BELOW WILL HAVE A SERIOUS ADVERSE IMPACT ON THE MEDICAL DEVICE INDUSTRY AND THE PUBLIC

The Circuit Court's interpretation of 35 U.S.C. § 271(e)(1) means that a patent owner is powerless to prevent marketing of an otherwise infringing medical device if that marketing is solely for uses reasonably related to the development and submission of information under the Federal Food, Drug, and Cosmetic Act. The immediate effect of this decision will, of course, be its significant economic consequences on the litigants, and on similarly situated litigants. The near term effects will predictably be the introduction of copy-cat medical devices during existing patent terms, undercutting the value of current patents unfairly. The longer term effects are, however, the most serious, not only for the companies affected, but also for the patients who might utilize those companies' products: This decision must, necessarily, significantly alter business planning in the medical device industry.

Innovation, in this field as in others, requires creativity, perception, hard work—all human qualities that will not disappear because of a court decision. Innovation also requires, however, money, often a great deal of money. Businesses can (and will) only devote large amounts of money to research and development if they can have some assurance that the fruits of that research will provide an adequate return to justify the cost. Here, the Circuit Court has reduced effective patent terms, during which research costs can be recovered, by as much

as five years or more. In some cases, the years denied protection are the most important in the product's life. Moreover, with respect to some types of medical devices, the decision has, as a practical matter, removed effective patent protection altogether. The ultimate effect of the Circuit Court's decision is predictable—medical device executives must now cut back on research and development expenditures.

An understanding of why the effect of the Circuit Court's decision is so significant requires an understanding of the particular characteristics of the medical device industry and of the system for regulatory approval of medical devices:

A. Characteristics of Medical Devices

The term "device" as defined by the Federal Food, Drug, and Cosmetic Act includes an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article" used for medical purposes. 21 U.S.C. § 321(h). This definition encompasses a wide variety of products, ranging from tongue depressors to sophisticated medical machinery. Consequently, medical devices are divided into three classes, with Class III encompassing the more sophisticated devices. *See* 21 U.S.C. §§ 360c-360e. The types of devices in Class III include the automatic implantable cardioverter defibrillator at issue in this litigation, certain orthopedic products manufactured by Zimmer, CAT-scans and other diagnostic machinery, and many other lifesaving medical devices.

B. Regulatory Approval of Medical Devices

Only Class III medical devices require premarket approval. *See* 21 U.S.C. § 360(e).[4] Within Class III, all

[4] Premarket clearance for such medical devices was first required in 1976 by the enactment of the Medical Device Amendments of 1976. Pub. L. No. 94-295, 90 Stat. 540 (1976).

new devices introduced after 1976 require premarket approval by the FDA. However, pre-1976 medical devices in Class III and devices that can be shown to be "substantially equivalent" to such pre-1976 devices only require premarket approval if the FDA, by regulation, specifically requires such approval. *See* 21 U.S.C. §§ 360c(f), 360e(a)-(b). Premarket approval, where required, involves submission to the FDA of safety and effectiveness test data, as well as other data and information. In some cases, a device manufacturer who argues that its device is "substantially equivalent" to a pre-1976 medical device and thus not subject to premarket approval may also be required to develop safety and effectiveness data to support that position. Testing of an unapproved medical device is permitted upon FDA clearance of an Investigational Device Exemption ("IDE"). *See* 21 C.F.R. Part 812 (1988).

When safety and effectiveness data are required, the same information must be developed and the same regulatory requirements apply for copies of existing, patented products as for new products. There are no abbreviated procedures available for establishing the safety and effectiveness of copies of patented devices as there are for the drug products to which the statute at issue was intended to apply. *See* 21 U.S.C. §§ 355(b)(2), 355(j).[5]

To generate the safety and effectiveness data required for FDA approval, medical devices must generally be used in a treatment context. That may mean permanent implantation of a device during its investigational stage. For example, hip stem replacements of the type produced by Zimmer must be implanted in patients in clinical trials of the devices. Development of necessary safety and effectiveness data may, with respect to some devices, require major purchases of the devices by hospitals or clinics, again during the investigational stage. For ex-

[5] *See* discussion in Section II, *infra*, regarding Congressional intent that Section 271(e)(1) should apply to drugs.

ample, diagnostic machines such as CAT-scans must be used in hospitals over an extended period of time to develop data for submission to FDA.

Zimmer's recent experience with a patented invention provides a good example of the length of time during which investigations sometimes must be conducted before FDA approval is obtained. Zimmer cooperated with two leading orthopedic surgeons to develop an innovative hip stem replacement known as the "Bias™ hip prosthesis." This patented medical device received FDA approval for use without bone cement in February 1989. The device, however, was introduced in the market for clinical testing purposes for use without bone cement in 1982, and the application for premarket approval was filed in 1984.

C. Sales of Medical Devices As Part of the Investigational Stage

The clinical testing necessary for obtaining FDA approval of Class III medical devices is also vitally important to develop a reputation for innovation and to control quality, points which are important for the subsequent success of the manufacturer's products (including devices other than the one under investigation). Moreover, clinical testing of medical devices—unlike the bioequivalence testing of drugs that Section 271(e)(1) was written to cover[6]—often involves substantial sales of the device being investigated. FDA regulations for medical devices allow medical device companies to recover their cost of manufacture, research, development, and handling of a device while it is being tested. 21 C.F.R. § 812.7(b) (1988).

A medical device manufacturer may not promote or commercialize an investigational medical device. Where individual devices are expensive and a large number of patients must be utilized to allow the company to develop

[6] *See* Section II.D *infra* for a discussion of bioequivalence testing of drugs.

statistically significant data to justify FDA approval, however, the dollar amount of sales for an investigational device can mount rapidly.

* * *

It is not difficult to predict the consequence if the Circuit Court's decision is allowed to stand. Patent infringers will enter the market for a product like the Bias™ hip prosthesis as soon as their copies of the patented products can be developed. They will, perfectly legitimately, file an IDE and begin selling their copy as part of their own investigations of the safety and effectiveness of the copy. The investigational process will necessarily stretch on for years to gather data on long term stability, even assuming good faith on the part of all concerned, but no actionable patent infringement will occur until the date of approval. (If the patent term expires before the date of approval, there may never be actionable infringement.) To take an example important to Zimmer—with many orthopedic manufacturers conducting potential clinical studies of a Bias™ hip, the number of patients receiving the innovative product will be substantial and Zimmer's "leap of faith" to develop an innovative product will, in the absence of patent protection, merely benefit all other orthopedic manufacturers who follow Zimmer's lead.

The characteristics of uses of medical devices make this effect particularly damaging to the innovator medical device industry. Unlike the situation with drugs (for which non-patient volunteers are utilized for bioequivalence testing), a patient receiving a hip stem replacement from a copier during the investigational period will not be available as a customer for the innovator if the copier can only be stopped at the point of approval of its product. No one is going to remove an implanted hip stem that is performing satisfactorily. That customer is irretrievably lost to the innovator. Similar effects are predictable with respect to high cost reusable machinery.

Such machinery may be extremely expensive, in some cases running more than one million dollars per unit, and a hospital may only be able to afford one such device. Consequently, investigational sales may successfully lock up the market for that device prior to FDA approval.

Innovation in the medical device industry is very rapid. Given the length of time required for FDA approval, many devices may be becoming obsolete by the time that the devices receive approval. Thus, the principal sales of those types of devices will be during the investigational period. Intraocular lenses are a good example of medical devices which have been primarily marketed during the testing period. It is not uncommon for an intraocular lens to be considered outdated by the time that lens is approved.

In a very innovative sector of the medical device industry, therefore, the Circuit Court's decision makes patent protection almost totally illusory. By the time a patent can be enforced (*i.e.*, the date of approval for the copier), the copier will surely have moved on to investigate (and in the process market) an updated product.

The effect of this decision on business planning in the medical device industry is self-evident. If patent protection for an innovation is significantly devalued, less can be spent on research and development. If innovator companies are generally the losers from the decision—as they undeniably are—and copiers are the winners, investors will put their money in copying companies, again diminishing available resources for innovation. Ultimately, the greatest loss will be to patients who might have benefited from innovation that will not occur.[7]

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[7] In addition, because this decision disadvantages innovation in the United States, which is now a leader in the development of new medical devices, the decision will have adverse trade consequences.

II. THE DECISION BELOW WAS IN ERROR

A. The Plain Meaning of the Statute is at Odds With the Circuit Court's Decision

Section 271(e)(1) in its present form states that:

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1).[8]

It is clear that courts are bound by the specific statutory language in construing statutory provisions. *See, e.g., United States* v. *James*, 478 U.S. 597, 604-606 (1986). Zimmer respectfully suggests that the ordinary reading of the quoted statutory language is that it grants a narrow exemption from patent infringement for developing information necessary to obtain approval for drugs and veterinary biological products.[9] Inexplicably,

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[8] The statute initially referred only to "a Federal law which regulates the manufacture, use, or sale of drugs." The term "or veterinary products" was added in 1988. Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988).

[9] As Lilly's petition for certiorari sets out and as discussed in Sections II(B) and II(C), *infra*, confirmation that that reading is the common one is found in the legislative history of Section 271(e)(1) as passed in 1984 and in discussions of commentators. Further confirmation is also found in the early legislative history of the 1988 amendment to Section 271(e)(1) which brought animal

however, the Circuit Court has read the provision as granting an exemption from patent infringement not only for developing information necessary to obtain approval of drugs and veterinary biological products but also for developing information necessary to obtain approval of a wide spectrum of other products, including medical devices and some food products and ingredients.[10]

The Circuit Court's interpretation undeniably requires a strained reading of the plain language of the statute. To bring medical devices within the ambit of the statute, it is necessary to find that the phrase "a Federal law which regulates the manufacture, use, or sale of drugs" is shorthand for the Federal Food, Drug, and Cosmetic Act and the Biologics Act of 1902 (the other statute under which FDA approves some (biological) drugs). This reading simply cannot be squared with the caveat in Section 271(e)(1), which explicitly refers to the "Federal Food, Drug, and Cosmetic Act."

Contrary to the Circuit Court's suggestion, this unusual reading of Section 271(e)(1) as covering products other than human and veterinary drugs cannot be justified by noting that Section 271(e)(1) uses the term "patented invention" rather than the term "patented drug." The use of the term "invention" is explicable by the fact that Congress was dealing not only with product patents but also with patents for drug compositions and patents for uses of drugs. Thus the term "patented drug" would have been potentially unclear, whereas the term "invention" clearly covers patents for drug products, composition, and use. Moreover, the term "patented invention" is the term used in 35 U.S.C. § 271(a) which Section 271(e)(1) modifies.[11]

drugs within the ambit of that section. *See* S. Rep. No. 448, 99th Cong., 2d Sess. at 13 (1986), describing the proposed amendment:

> This section amends Section 271 of Title 35 to provide that it is not an act of patent infringement to make or use an animal drug or veterinary biological for purposes reasonably related to developing information for a submission to FDA. *A similar provision applies to human pharmaceuticals.*

(Emphasis added.)

[10] The Court's reading also changes patent infringement law with respect to food additives, color additives, and some food products as to which information must be submitted to FDA to justify a change in a food standard. *See* 21 C.F.R. §§ 71.1, 171.1 (1988) (describing data submission requirements for color additive petitions and food additive petitions respectively); 21 C.F.R. § 130.17 (1988) (temporary permits allowing marketing of food to gather information to support a petition to amend a food standard).

B. The Circuit Court's Interpretation is Inconsistent with Congress' Clear Intent

The Circuit Court's interpretation also violates the well-established principle of statutory construction that courts are required to defer to the intent of Congress if there is any doubt about the meaning of the words. *See, e.g., Mackey* v. *Lanier Collections Agency & Service, Inc.*, —— U.S. ——, 108 S.Ct. 2182, 2191 (1988). The Circuit Court's decision seems to be based on its own view of possibly applicable policy considerations (Pet. App. 7a). The court, however, was not free to substitute its policy choices for those of Congress and rewrite the legislation. *See, e.g., United States* v. *Rutherford*, 442 U.S. 544, 555 (1979).

The legislative history of Section 271(e)(1) as enacted[12] unambiguously demonstrates that Section

[11] Section 271(a) states that "Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent."

[12] It is appropriate to look at Congress' intent in 1984 in enacting Section 271(e)(1) because the original version of Section 271(e)(1) included both the disputed phrase "a Federal law which regulates the manufacture, use, or sale of drugs" and an explicit reference to the "Federal Food, Drug, and Cosmetic Act." The 1988 amendment does not change the analysis. To the contrary, it con-

271(e)(1) was intended to apply only to drugs. Thus, in a House Report, the Committee stated that "the only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 8 (1984). (Bioequivalence is equivalence in the rate and extent of absorption of a drug. *See* 21 U.S.C. § 355(j)(7)(B).) The same Report also refers to "provisions of the bill which permit the limited testing of drugs while they are on patent in order to assist in the preparation of an abbreviated new drug application." *Id.* at 29. *See also* 130 Cong. Rec. H8,708 (daily ed. Aug. 8, 1984) (statement of Rep. Kastenmeier) (provision will allow generic manufacturer to "obtain a supply of a patented drug product during the life of the patent and conduct tests using that product"); *id.* at H8,712 (statement of Rep. Kindness) ("this bill would provide that the generic drug manufacturers can start playing around with the drug on which the patent is about to expire within a year").

That this provision was understood by Congress to differentiate between pharmaceuticals on the one hand and all other types of patented products on the other is made clear in the statement of Rep. Moorhead, 130 Cong. Rec. H9,143 (daily ed. Sept. 6, 1984), who criticized the provision for that reason, saying:

> There is no legitimate basis for distinguishing between the exclusionary rights accorded a pharmaceutical manufacturer during the patent term and those enjoyed by any other patent holder.

If the legislative history were not already clear enough, Congress' intent is further elucidated in the

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firms that Congress intended to limit Section 271(e)(1) to specifically identified products, *i.e.*, human drugs and veterinary drugs and biologicals.

amicus brief in support of Lilly's request for rehearing en banc filed by Senator Hatch, the principal Senate author of the 1984 legislation, and Rep. Moorhead, a primary floor manager of the bill in the House. In that brief, Senator Hatch and Rep. Moorhead reiterate that Section 271(e)(1) was intended to apply only to drugs. Brief of Senator Hatch and Representative Moorhead at 2.

C. The Medical Device Industry Had No Notice That Section 271(e)(1) Might Be Interpreted To Apply to Medical Devices

The extent of the Circuit Court's departure from both the words of the statute and Congress' expressed intent is suggested by the fact that its interpretation, extending Section 271(e)(1) to medical devices and other products, was totally unexpected by those in the medical device manufacturing community familiar with the statute. There had been no indication anywhere in the legislative history that Section 271(e)(1) was intended to apply to medical devices. In fact, the legislative history of Section 271(e)(1) made no reference at all to medical devices, and the medical device industry had no input on the issues relevant to extending Section 271(e)(1) to medical devices.[13]

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[13] Some innovator firms with medical device subsidiaries were involved in the negotiations which led to the Drug Price Competition and Patent Term Restoration Act of 1984. Thus, for example, Bristol-Myers Co. is cited as an active participant in the negotiations that led to the 1984 Act, as are Johnson & Johnson and American Home Products, other health care companies that have both drug and device subsidiaries. *See, e.g.*, 130 Cong. Rec. S10,504 (daily ed. Aug. 10, 1984) (statement of Sen. Hatch). This may account for the inclusion of medical devices in the patent term restoration provisions of the Act. However, there is no evidence that these companies expressed any views on the advisability of applying Section 271(e)(1) to medical devices. Nor is there record in the legislative history of Section 271(e)(1) of any involvement by proponents of easier market access for generic copies of medical devices.

If Congress had intended to include medical devices within the ambit of Section 271(e)(1), it is inconceivable that medical device patent holders would have had no involvement in the process and no opportunity to provide Congress with information on the significant, adverse effects of such legislation on a vitally important high technology industry and on the public. The conclusion that there would have been input from the medical device industry if Section 271(e)(1) was intended to reach medical devices is reinforced by the fact that the legislative history of the 1984 legislation clearly shows that Section 271(e)(1) was drafted after extensive input from both generic and innovator *drug* manufacturers. *See, e.g.*, 130 Cong. Rec. H9,123 (daily ed. Sept. 6, 1984) (statement of Rep. Gore) (legislation "has been a very difficult and complex effort to strike a balance between the interests of consumers and generic drug companies, on the one hand, . . . [and] the innovators of new drugs").

The Circuit Court's reading of Section 271(e)(1) was all the more unexpected because it departs from the reading of the statute both by commentators and by the only other courts to have considered the matter. To our knowledge, prior to this decision, no commentator had ever read Section 271(e)(1) to apply to any product other than drugs (and since 1988 to veterinary drugs and biological products). To the contrary, several commentators agreed that the 1984 legislation "is limited to human drugs, and does not include medical devices . . . food additives, color additives, or other related products." Flannery & Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 307-08 (1985); *accord*, A. Fox & A. Bennett, *The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984* 178, 187 (1987).

Similarly, the few judges to have considered the issue prior to the Circuit Court's ruling all read Section 271(e)(1) as limited to drugs. In the instant case, both the district court and the panel of the Circuit Court which denied Medtronic's motion to stay the injunction entered below pending appeal found that Section 271(e)(1) applies only to drugs. The only other district court opinion to discuss the issue states that "[i]t is also clear that section 271(e)(1) applies only to drugs, not to medical devices." *Scripps Clinic & Research Foundation* v. *Baxter Travenol Laboratories, Inc.*, 7 U.S.P.Q.2d 1562, 1565 (D.Del. 1988) (dictum).

D. The Intended Effect of Section 271(e)(1) as Applied to Drugs Differs From The Effect Of Its Application To Medical Devices

Given the significant differences between drugs and devices, and between applicable regulations, none of the problems involved in extending Section 271(e)(1) to medical devices apply if that section is limited to its clear language and read to apply only to drugs (and veterinary biological products). Unlike many medical devices that are durable and subject to either continued use by a patient (for example, implants) or multiple uses (for example, x-ray or ultrasound machines), most drugs are subject to one-time use because they are administered to the body through ingestion, injection, or absorption through the skin. Likewise, the regulation of drugs is substantially different from the regulation of medical devices, especially with respect to generic copies of approved drugs.

In Title I of the Drug Price Competition and Patent Term Restoration Act of 1984, Congress amended the drug approval statute to allow approval of generic copies of approved drugs on the basis of "bioequivalence" tests rather than the full safety and effectiveness trials otherwise necessary to justify FDA approval of a drug prod-

duct.[14] In these tests, the generic company administers its generic copy to a limited number of human subjects (who usually do not have the illness for which the drug is indicated)[15] and, in the same test, administers the innovator product to human test subjects. It then determines whether the rate and extent of absorption of its drug and that of the innovator drug are equivalent. *Cf.* 21 U.S.C. § 355(j)(7) (definitions of bioavailability and bioequivalence). Upon submission of test results showing bioequivalence, and data concerning the chemistry, manufacturing, and labeling of its drug, the generic drug manufacturer may obtain approval of either an abbreviated new drug application submitted pursuant to 21 U.S.C. § 355(j) or a "paper" new drug application submitted pursuant to 21 U.S.C. § 355(b)(2).

The main effect of Section 271(e)(1) in the context of drugs is to allow the completion of such bioequivalence testing prior to patent expiration. Although Section 271(e)(1) would allow non-bioequivalence testing of generic drugs if that testing were designed to obtain drug approval, the ordinary route to approval of a copy of a patented drug would be through bioequivalence testing, not through full clinical trials. Drug testing that would involve infringement of a drug patent but would not involve testing of a generic drug would be rare.

Unlike clinical trials of medical devices that infringe patents, bioequivalence testing of generic drugs has a *de minimis* effect on manufacturers of patented drugs. Since

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[14] *See* 21 U.S.C. § 355(j). Title I is undeniably applicable only to drugs and not medical devices. Thus, Congress clearly intended some provisions of the 1984 legislation to apply to drugs only and some to apply to drugs and devices. Congress spoke clearly when it intended to include devices. *See, e.g.*, 35 U.S.C. § 156(f).

[15] Test subjects who are ill will generally be used in bioequivalence tests only for drugs (such as cancer drugs) which are too toxic to be administered ethically to persons who will not receive a benefit from their use.

bioequivalence testing generally does not involve treatment of patients or permanent use of the product, bioequivalence testing does not take potential customers away from manufacturers of patented drugs during the life of the patent. Moreover, bioequivalence testing does not allow generic manufacturers to profit from copying a patented drug during the life of the patent because, as a practical matter, bioequivalence testing is never the subject of requests to FDA to allow companies to seek reimbursement of their costs of treatment of test subjects. Therefore, despite Section 271(e)(1), manufacturers of patented drugs continue to enjoy exclusive sales during the life of the patent.

In fact, Congress specifically addressed the question of whether Section 271(e)(1) would result in a significant diminution of a drug patent owner's rights. Congress determined that any effect would be minimal because all that would be involved was bioequivalence testing. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2 at 30.

Moreover, when Congress limited the scope of patent protection for human drugs in 1984 and for veterinary drugs in 1988, it provided some offsetting patent benefits to the innovator manufacturers, benefits that were *not* provided to innovator device manufacturers.[16] In 35 U.S.C. § 271(e)(2), Congress provided that it would be an act of infringement to submit an abbreviated new drug application ("an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act") or a paper new drug application ("an application . . . described in section 505(b)(2) of such Act") with the intention of obtaining marketing approval before patent expiration. Likewise, when Congress created an infringe-

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[16] Patent term restoration was made available for some medical devices, but included limitations so that not all medical devices with patent terms effectively devalued by the Circuit Court's decision would be eligible for restoration. *See* 35 U.S.C. § 156(a).

ment exception applicable to animal drugs and veterinary biological products by adding them to Section 271(e)(1), it also provided that it would be an act of infringement to submit an abbreviated new animal drug application ("an application under section 512 of such Act") with the intention of obtaining marketing approval before patent expiration. 35 U.S.C. § 271(e)(2)(B).

Congress also required that an applicant submitting an abbreviated new drug application or new animal drug application with an intent to market the product in defiance of a patent claim notify the patent holder of the submission and of the basis for the copier's belief that the patent is invalid or not infringed. 21 U.S.C. §§ 355(j)(2)(B), 360b(n)(2)(A). Then, if the patent holder sues within 45 days of receipt of the notice, FDA approval of the abbreviated new drug application or abbreviated new animal drug application is automatically delayed for 30 months. 21 U.S.C. §§ 355(j)(4)(B)(iii), 360b(c)(2)(D)(iii). Thus, specific protections for the human *drug* patent holder were incorporated into the 1984 statute, and similar protections were incorporated for animal drug patent holders in 1988. No such similar protections were added for the medical device patent holder.

CONCLUSION

For all the foregoing reasons, Zimmer respectfully submits that the Court should grant Lilly's petition for a writ of certiorari. Moreover, because the Circuit Court's decision so clearly departs from the plain language of the statute and clear legislative intent, that decision should be summarily reversed.

Respectfully submitted,

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